

REMARKS

Claims 1, 3, 4 and 10-13 are pending in the present application. Claim 2 was previously cancelled and claims 5-9 and 14-44 previously withdrawn from consideration. In this response, no claims have been amended, cancelled, or added. Accordingly, claims 1, 3, 4, and 10-13 remain under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Rejections Under 35 USC §103(a)

Claims 1, 3, 4 and 10-13 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. 5,962,532 to Campbell (“Campbell”) in view of Wholehealthmd. Specifically, the Office Action states that while neither reference teaches a kit and a separately packaged second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap solution to remove the irritant effect so as to allow the effect of capsaicin to be achieved. The Office Action further states that the soapy solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect.

Applicants strongly disagree that a *prima facie* case of obviousness has been properly established. In order to set forth a *prima facie* case of obviousness, three basic criteria must be met, one of which is that the prior art references when combined must teach or suggest all the claim limitations (see MPEP §2143). Among other things, claim 1 requires a kit, including as separately packaged components, a capsaicin composition and a second cleansing composition in which the capsaicin has a solubility of at least about 10% w/w. The claim also requires the second composition to cleanse the bodily surface by removing the capsaicin remaining on the skin after application of the first composition.

The Examiner acknowledges that Campbell and Wholehealthmd do not describe a kit or the capsaicin and cleansing compositions as separately packaged components (see Office Action dated March 14, 2008, page 3, paragraph 6). Campbell also fails to describe a second composition

for cleansing a bodily surface comprising a substance in which the capsaicin has a solubility of at least about 10% w/w. Wholehealthmd does not cure this defect.

Applicants respectfully remind the Examiner that data supporting the contention that capsaicin is not at least 10% soluble in warm soapy water was provided in the Supplemental Amendment dated November 9, 2005 for this application. The data established that capsaicin is insoluble (less than 0.1% w/w) in warm soapy water at three different concentrations of antibacterial handsoap, even with frequent sonication over a 20 minute timeframe. A copy of the signed report describing the experiments that were performed to determine the solubility of capsaicin in warm soapy water may be found in Exhibit A of the Supplemental Amendment.

Additionally, the solution to the problem of eliminating the irritant effects of capsaicin provided by Campbell differs from that disclosed by Wholehealthmd. Campbell describes administering a narcotic analgesic to counteract or neutralize the effect of the capsaicin remaining on the skin, not removing capsaicin by washing (as described by Wholehealthmd). As stated at column 4, lines 46-51 of Campbell, "If some "breakthrough pain" occurs despite the anesthetic, this pain may be treated by administering an analgesic such as a narcotic analgesic (i.e., various alkaloids of opium, such as morphine, morphine salts, and morphine analogues, such as normorphine)." Given that Campbell discloses such a different approach in handling the irritant effects of capsaicin on the skin, it is argued that one of skill would not seek to combine it with Wholehealthmd.

One of skill would also not look to combine Campbell, or any other reference describing a capsaicin-containing composition, with Wholehealthmd, because capsaicin is not water soluble. According to the Merck Index (14th Edition, p. 1765), capsaicin is considered to be insoluble in water. Based on this information, one of skill would not use water to remove capsaicin from the skin. The instant Office Action also emphasizes that the soapy solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect (see page 3, paragraph 6).

At least in view of the above, withdrawal of rejection under 35 U.S.C. § 103(a) of claim 1 and claims 3, 4, and 10-13, which depend therefrom, is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524522000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By 
Lisa A. Amii

Registration No.: 48,199
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5674